



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 100, 101, and 104

[Docket No. FDA-2016-N-0011]

Food Labeling; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food labeling regulations by redesignating a provision, updating any references to that provision to reflect the redesignation, and revising the section heading. The rule does not alter the content or application of the redesignated provision in any substantive manner. This action is editorial in nature and is intended to provide clarity and consistency to our regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Carole Adler, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

The Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1451 et seq.) requires certain consumer commodities sold in interstate commerce to be honestly and informatively labeled to facilitate value comparisons and enable consumers to make informed choices. FDA administers

and enforces the FPLA with respect to drugs, cosmetics, medical devices, and certain foods. Pursuant to our authority under FPLA, FDA issued certain food labeling regulations, including specifications regarding the statement of identity and the net quantity of contents statement, which must be present on the labels of most packaged foods. Our regulations affecting the declaration of a food product's net quantity of contents are currently located in § 101.105 (21 CFR 101.105). Section 101.105 specifies how the net quantity of contents must be expressed on the package, including the required units of measurement, wording, typeface, and size to be used in the declaration, as well as the location of the declaration on the label or package. Currently, § 101.105 requires that the units of measurement be expressed using the most appropriate units of the customary inch/pound (avoirdupois) system carried out to not more than two decimal places, as applicable.

In the Federal Register of May 21, 1993 (58 FR 29716), we proposed to amend our food labeling regulations to require that the net quantity of contents declaration be expressed using the most appropriate units of both imperial units (inches/pounds) and the metric system (International System of Units (SI)). The rule also proposed to provide examples of the quantity of contents declaration, include the SI equivalents to the avoirdupois terms used in the regulation, provide a specific conversion chart for use in calculating the conversion between the two systems of measurement, include SI terminology, provide exemptions from SI labeling requirements, permit the expression of the net quantity of contents to be carried out up to three decimal places, and make the SI declaration of the net quantity of contents on random weight packages optional. Additionally, the rule proposed certain technical amendments, including redesignating § 101.105 as new § 101.7, revising the section heading to correct the title of the section, and making other editorial changes to the net quantity of contents regulations. In the

Federal Register of April 22, 2003 (68 FR 19766), we announced our intent to withdraw the proposed rule, along with several other unrelated proposed actions that had been published more than 5 years before the withdrawal, but never finalized. The withdrawal was part of an overall regulatory reform initiative to reduce our regulatory backlog and focus our resources on higher priority regulations.

Through this final rule, we are making some of the same technical amendments to the declaration of net contents provision that were proposed in 1993. However, we are not proposing at this time to reinstitute rulemaking proceedings concerning the remaining amendments proposed in 1993, such as those pertaining to the declaration of net quantity in SI units or those modifying the expression of net quantity in decimal fractions.

II. Provisions of Technical Amendments

We are making technical amendments in our regulations at parts 1, 100, 101, and 104 (21 CFR parts 1, 100, 101, and 104) to redesignate § 101.105 as new § 101.7, update references in other provisions to reflect this redesignation, and revise the section heading of the redesignated provision. Nothing in these technical amendments is to be construed as modifying the applicability of the current regulations affecting the declaration of net quantity of contents.

A. Redesignation

FDA is amending the food labeling provisions in § 101.105 by redesignating § 101.105 as new § 101.7. Section 101.105 is currently located in part 101, subpart G, which is entitled "Exemptions From Food Labeling Requirements." However, § 101.105 contains no information pertaining to when a food is exempt from a declaration of the net quantity of contents. Instead, § 101.105 establishes general provisions for the declaration of the statement of net quantity of contents on the labels of most packaged foods. By redesignating § 101.105 as new § 101.7, we

are moving the provision to subpart A, entitled "General Provisions." Subpart A provides general food labeling regulations and is a more appropriate location for a provision regulating the declaration of net quantity of contents.

B. Revising Section Heading

We also are revising the section heading of new § 101.7 to read: "Declaration of net quantity of contents" instead of "Declaration of net quantity of contents when exempt." The revised heading, by removing any reference to exemptions, is more reflective of the section's general provisions for the declaration of the statement of net quantity of contents on all food labels. The revised heading does not alter the substance of the provision.

C. Revising References

Several existing regulations refer to § 101.105. Therefore, because we are redesignating § 101.105 as a new § 101.7, we are making corresponding editorial changes to reflect the redesignation in parts 1, 100, 101, and 104. These corresponding changes replace any mention of § 101.105 with § 101.7.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are nonsubstantive and provide only technical changes to redesignate an existing regulation, make corresponding changes to other regulations to reflect the redesignated section number, and make an editorial change to the section heading. These technical amendments are being made to improve the accuracy of our regulations.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 100

Administrative practice and procedure, Food labeling, Food packaging, Foods, Intergovernmental relations.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration amends 21 CFR parts 1, 100, 101, and 104 as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342i, 343, 350c, 350d, 350e, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.1 [Amended]

2. Amend § 1.1(c) as follows:

- a. Remove "101.105(f)" and add in its place "101.7(f)".
- b. Remove "101.105(i)" and add in its place "101.7(i)".

c. Remove "101.105(j)" and add in its place "101.7(j)".

d. Remove "101.105(o)" and add in its place "101.7(o)".

§ 1.20 [Amended]

3. In § 1.20, by removing "§ 101.105(f)" and adding in its place "§ 101.7(f)".

§ 1.24 [Amended]

4. Amend § 1.24 as follows:

a. Remove "§ 101.105" in paragraph (a)(2) and add in its place "§ 101.7".

b. Remove "§ 101.105(b)(2)" wherever it appears and add in its place "§ 101.7(b)(2)".

c. Remove "§ 101.105(f)" wherever it appears and add in its place "§ 101.7(f)".

d. Remove "§ 101.105(j)" wherever it appears and add in its place "§ 101.7(j)".

e. Remove "§ 101.105(j)(1)" wherever it appears and add in its place "§ 101.7(j)(1)".

PART 100--GENERAL

5. The authority citation for part 100 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 337, 342, 343, 348, 371.

§ 100.155 [Amended]

6. Amend § 100.155 in paragraphs (a) and (b) by removing "§ 101.105" and adding in its place "§ 101.7".

PART 101--FOOD LABELING

7. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42

U.S.C. 243, 264, 271.

§ 101.2 [Amended]

8. Amend § 101.2 in paragraph (c) introductory text by removing "§ 101.105(h)(1)" and adding in its place "§ 101.7(h)(1)".

§ 101.105 [Redesignated as § 101.7]

9. Redesignate § 101.105 as § 101.7.

10. Revise newly designated § 101.7 section heading to read as follows:

§ 101.7 Declaration of net quantity of contents.

* * * * *

§ 101.13 [Amended]

11. Amend paragraphs (d)(2), (h)(4)(i), and (i)(2) by removing "§ 101.105(i)" and adding in its place "§ 101.7(i)".

§ 101.30 [Amended]

12. Amend § 101.30(g) by removing "§ 101.105(i)" and adding in its place "§ 101.7(i)".

PART 104--NUTRITIONAL QUALITY GUIDELINES FOR FOODS

13. The authority citation for part 104 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 371(a).

§ 104.5 [Amended]

14. Amend § 104.5(b) by removing "§ 101.105" and adding in its place "§ 101.7".

Dated: August 16, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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